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Coats & Bennett/Medtronics
1400 Crescent Green
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Cary, NC 27518

APR 21 2008 In Re: Patent Term Extension
Application for
U.S. Patent No. 6,235,030

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,235,030, which claims the medical device X-STOP® Interspinous Process Decompression System, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,053 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,053 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 1, 2007 (72 Fed. Reg. 30596), would be 1,166 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,538 - 578) + 686 \\ &= 1,166 \text{ days (3.2 years)}\end{aligned}$$

Since the regulatory review period began October 22, 1999, before the patent issued (May 22, 2001), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 22, 1999, to and including May 22, 2001, is 578 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,166 days, would extend the patent from January 2, 2017 to May 21, 2018, which is beyond the 14-year limit (the approval date is November 21, 2005, thus the 14 year limit is November 21, 2019). The period of extension is thus limited to 1,053 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, January 2, 2017, to and including November 21, 2019, or 1,053 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:

6,235,030

Granted: May 22, 2001

Original Expiration Date¹: January 2, 2017

Applicant: James F. Zucherman et al.

Owner of Record: Kyphon Inc.

Title: Spine Distraction Implant

Product Trade Name: X-STOP® Interspinous Process Decompression System

Term Extended: 1,053 days

Expiration Date of Extension: November 21, 2019

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Tidwell
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: X-STOP® Interspinous
Process Decompression
System
FDA Docket No.: 2006E-0259